

## **EXHIBIT 7**

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	
	)	
	)	
	)	MDL No. 1456
	)	Civil Action No. 01-12257-PBS
<b>THIS DOCUMENT RELATES TO:</b>	)	
	)	
<i>United States of America ex rel. Ven-a-</i>	)	
<i>Care of the Florida Keys, Inc., v. Abbott</i>	)	
<i>Laboratories, Inc., and Hospira, Inc.</i>	)	
Civil Action No. 06-11337-PBS	)	

**DECLARATION OF MELBOURNE A. NOEL**

I, Melbourne A. Noel, do hereby declare pursuant to 28 U.S.C. § 1746 as follows:

1. I am a Senior Contracts Attorney in the Office of General Counsel of the Department of Veterans Affairs (VA), and I am stationed at the VA National Acquisition Center (NAC) in Hines, IL. My responsibilities include advising NAC managers and contracting officers (COs), consulting with managers of the Pharmacy Benefits Management Strategic Healthcare Group (PBM) of the Veterans Health Administration (VHA), and chairing a Policy Group that guides administration of 38 U.S.C. 8126. The information set forth in this Declaration is based on my personal knowledge, on information obtained by me from officials of VA acting pursuant to their official duties, and on records generated by the VA in the course of its statutorily mandated activities.

2. I have reviewed a copy of the Defendant Abbott Laboratories Inc.'s First Set of Requests For Production of Documents and Tangible Things to Plaintiff United

States of America. The following paragraphs describe the relevant VA activities that generate potentially responsive documents and the nature of the documents involved.

A. Veterans Health Administration

3. The Veterans Health Administration (VHA) provides medical care directly to the Nation's veterans through a network of 21 Veterans Integrated Service Networks (VISN), consisting of 163 hospitals, and hundreds of clinics nationwide at a total cost of about \$30.8 billion in FY 2005. Virtually every one of these entities conducts drug purchasing activities using NAC contracts, making VHA one of the largest purchasers of drugs in the United States. All of these entities generate and maintain documentation concerning their many thousands of drug purchases, which would include "Communications involving . . . (ii) drug pricing, or (iii) the acquisition costs of Providers for drugs," within the meaning of Abbott's request for documents. See Request #19; and see Request #120. The task of searching the files of these entities and producing responsive information would be enormous, and would entail many thousands of hours of VA employee time—resources which inevitably would be diverted from the VHA's central mission of providing health care to the Nation's veterans.

4. In addition, VHA provides an outpatient pharmacy benefit to veterans through seven VA Consolidated Mail-Out Pharmacies (CMOPs) around the country. (One CMOP is currently off-line for equipment installation.) The CMOPs purchase large quantities of drugs through the NAC contracts on a "just in time" schedule, and each

CMOP routinely handles more than 60,000 prescriptions per day (approximately 400,000 total scripts per day for the entire system). Huge electronic files of drug purchasing and dispensing data are maintained by the CMOPs.

5. An additional repository of information concerning VA drug purchasing information is the Pharmacy Benefits Management Strategic Healthcare Group (PBM), a subpart of the VHA which assists in the administration of VA drug purchasing activity. The VA PBM generates and maintains various categories of information concerning drug prices or provider acquisition cost, including the following:

- a. Notices to field medical activities of FSS drug contracts, Blanket Purchase Agreements, National Committed Use contracts, and contract modifications;
- b. FSS drug price information (all of which is available on the VA's web site)
- c. Price data relating to Blanket Purchase Agreements and National Committed Use contracts;
- d. Files concerning drug class reviews;
- e. The PBM Outpatient Prescription Database, which includes acquisition cost data from all VA entities that purchase pharmaceuticals;
- f. The PBM Prime Vendor Database, consisting of purchase data (including price data) submitted by Prime Vendors concerning purchases by VA entities.
- g. All annual non-Federal Average Manufacturer Price reports filed by manufacturers for every covered drug since 1992, pursuant to 38 U.S.C. § 8126.

6. The PBM also administers a VHA national formulary of drugs that VHA physicians are expected to use. Since a drug's cost is considered in deciding whether to include the drug on the VA formulary, files relating to formulary decision making are

arguably within the scope of Abbott's document request. In addition, prior to 2006, each of the VHA's 21 VISNs administered its own regional formulary. These regional formularies reflected the national formulary but were independent with regard to other drug items not classified under the "closed" portions of the national formulary. Files of the regional formularies may still exist.

7. The burden associated with retrieving, searching through, and producing responsive documents as described above would be extraordinary. Hundreds of VHA hospitals and health clinics would be required to retrieve records concerning their routine drug purchases, search through those records, and make them available to defendants. Production of the PBM information described in paragraph 5 above would also be extremely time-consuming and burdensome.

B. National Acquisition Center

8. The National Acquisition Center (NAC), located in Hines, Illinois, negotiates, awards, and administers contracts for the purchase of various health care services and products, including pharmaceuticals. The NAC administers several programs that impact drug purchasing, described below.

National Committed Use Contracts

9. A National Contracting Service team at the NAC negotiates, awards, and administers National Committed Use contracts. These contracts provide generally that VA will commit to purchasing from one or two vendors all of its requirements (presented in solicitations as estimated volumes) for specified pharmaceutical products, and in return

the awarded vendor(s) will agree to supply each product at a favorable awarded price that results from the competitive process. The NAC has been awarding National Committed Use contracts since approximately 1995; there are currently about 100 to 150 such contracts in effect. The typical contract file includes documentation relating to the negotiation, award, and administration of the contract, and these files normally contain information and communications regarding drug prices and acquisition costs.

#### Federal Supply Schedule

10. The Federal Supply Schedules (FSS) program was established by Congress to authorize the General Services Administration (GSA) to establish government-wide contracts for services and products. See 41 U.S.C. 259(b) and 40 U.S.C. 501; 41 C.F.R. § 101-25.203. GSA has delegated to VA the responsibility for establishing a Federal Supply Schedule for pharmaceuticals and drugs. All Federal agencies are permitted to obtain drugs needed for their healthcare programs from FSS contracts. Billions of dollars in federal drug purchases are made annually through this program.

11. The VA FSS drug contracting program is administered by the Federal Supply Service pharmaceuticals contracting team at the NAC, which negotiates and administers contracts with drug manufacturers for placement of drugs on the FSS. The NAC currently has active FSS contracts with roughly 300 drug manufacturers. Hundreds more contract files are in storage. The typical FSS contract file is substantial, and includes documents and data concerning solicitation, contract negotiation, contract award, and contract administration. Contract files include information disclosed by the

manufacturer concerning contract prices negotiated between the manufacturer and specific non-federal customers, considered by the manufacturer to be confidential business information.

Federal Ceiling Price Agreements

12. The NAC's Federal Supply Service also executes, maintains, and administers Master Agreements and Pharmaceutical Pricing Agreements pursuant to Section 603 of the Veterans Health Care Act of 1992, 38 U.S.C. § 8126. This statute requires that, as a condition of participation in the Medicaid program, all covered drug manufacturers shall enter into a Master Agreement with VA under which a Pharmaceutical Pricing Agreement is executed establishing a minimum discount for covered drugs purchased by VA, the Department of Defense, the Public Health Service (including the Indian Health Service), and the Coast Guard. Participating manufacturers report their non-federal average wholesale pricing information for each separate NDC package of every covered drug to VA in an annual report, due November 15 of each year. Based on this information, VA then computes federal ceiling prices that are put into effect for the following calendar year. The four eligible Federal agencies can then purchase covered drugs at the Federal ceiling prices (or lower negotiated prices) under agency depot contracting systems or via the FSS.

13. The contract files generated by the Federal Ceiling Price Program are substantial. They include agreements, administrative correspondence and wholesale

pricing data reports. Currently, there are 230 Master Agreements and an equal number of Pharmaceutical Pricing Agreements in effect.

Prime Vendor Contracts

14. The NAC's National Contracting Service also awards and administers pharmaceutical prime vendor contracts (PPV) with wholesale drug distributors for "just in time" delivery of pharmaceutical products to Federal agencies at the prices set forth in the FSS or in National Committed Use contracts (described above). A manufacturer having a contract with the VA for the supply of pharmaceutical products almost always has an arrangement with the prime vendor for the distribution of the products through the VA PPV contract. The Federal agencies that utilize the VA PPV are VA, the Indian Health Service, and the Bureau of Prisons. In 2005, over \$4 billion in sales were made through the PPV contract, of which about \$3.5 billion represented sales to VA.

15. The PPV contract files include documents and information concerning solicitation and award, plus additional information regarding the administration of each contract, going back to 1993. Pricing data from the FSS and National Committed Use contracts is updated by the PBM and transmitted to the PPV on a daily basis.

D. Conclusion

16. In summary, it would be an enormous task for VA to search for, retrieve, and produce all VA documents responsive to Abbott's request for documents. I believe

such an effort would require VA personnel to devote thousands of hours of time to the effort. This would be very disruptive to VA's primary mission of serving our Nation's veterans and providing support to other Federal agencies in their public service missions.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on September 15, 2006

/s/ Melbourne A. Noel

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Melbourne A. Noel  
VA Office of General Counsel